

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur STANDARD OPERATING PROCEDURE	
Title: Protocol for high level disinfectant	
SOP Number:SOP/Micro/BMW/05	Pages:07
Revision Numbers:0/0	Department:Microbiology
Effective Date:26/05/2018	Replaces:NIL



1. Disinfection is a process where most microbes are removed from defined object or surface, except bacterial spores. **High level disinfection** is that which kills all microorganism and high number of bacterial spores.

2. Classification of Disinfectants

(a) High Level Disinfectants:-

- They destroy all microorganisms including vegetative bacteria, most bacterial spores, fungi, viruses including enteroviruses and mycobacterium tuberculosis except some bacterial spores. Ex.: 2% Glutaraldehyde, Ethylene Oxide, 1% Sodium Hypochlorite (10,000ppm of chlorine)
- Used for semi critical instruments and equipment's (those that are in contact with intact mucous membrane without penetration)
- For gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, respiratory therapy equipment's.

(b) Intermediate Level Disinfectants:-

- They destroy vegetative bacteria, Mycobacterium tuberculosis, most viruses e.g. enteroviruses and fungi but not bacterial spores. Ex.: Isopropyl alcohol (70%), ethyl alcohol, sodium hypochlorite (0.1%), Chlorhexidine, hydrogen peroxide, phenolic solutions.

(c) Low Level Disinfectants:-

- They destroy most vegetative bacteria, fungi and enveloped virus e.g. HIV but will not kill bacterial spores, Mycobacteria and non-enveloped viruses like enterovirus. Ex: Quaternary ammonium compounds like benzylkonium chloride, some soaps.

3 Guidelines for Selection of Disinfectants:-

There is no ideal disinfectant. Each application requires careful view of following:

- Type and number of organisms.
- Type and amount of organic matter
- Contact time
- Type of surface (Rough / Corrugated)
- Type of water (hard / soft)
- Manufacturers data on efficacy
- Safety and environmental aspects (chlorine is not free from toxicity)
- Cost, shelf life and convenience of use
- Residual activity

4. General Principles while Using a Hospital Disinfectant

- It is most important that an item or surface be free from visible soil and other items that might interfere with the action of the disinfectant, such as adhesive products, before a disinfectant is applied, or the disinfectant will not work
- A hospital approved disinfectant may be used for equipment that only touches intact skin
- It is important that the disinfectant be used according to the manufacturer's instructions for dilution and contact time
- Minimise the contamination levels of the disinfectant solution and equipment used for cleaning. This can be achieved by ensuring proper dilution of the disinfectant, preparing the disinfectant fresh before use, frequently changing the disinfectant solution and by not dipping a soiled cloth into the disinfectant solution (i.e., no 'double-dipping')
- Personal protective equipment should be worn appropriate to the product(s) used
- There should be a quality monitoring system in place to ensure the efficacy of the disinfectant over time (Vendors may also be asked to provide a quality test certificate for each batch for hospital records)

Important: The physical characteristics of the chemical should be considered before choosing a chemical. For example, even though alcohol is a rapid acting intermediate to HLD it is not suitable for disinfection of large surface areas due to rapid evaporation and flammability. Although chlorine is low cost HLD, it is highly corrosive to metals in concentration required for HLD. If disinfectants mentioned in this document are to be used for purposes other than those mentioned, guidance regarding the same should be taken before making a decision.

Table 1. Spaulding's classification of medical devices

Clinical device	Definition	Example	Infectious risk	Reprocessing procedure
Critical device	Medical device that is intended to enter a normally sterile environment, sterile tissue, or the vasculature	Surgical instruments	High	Sterilization by steam, plasma, ethylene oxide (ETO)
Semi-critical device	Medical device that is intended to come in contact with mucous membranes or minor skin breaches	Flexible endoscope	High, intermediate	Sterilization desirable; high-level disinfection acceptable
Non-critical device	Medical device that comes in contact with intact skin	BP cuff, ECG electrodes	Low	Intermediate or low level (hospital disinfectant with tuberculocidal claim)

Table 2 - Common High level disinfectants

Name of Disinfectant	Method of Dilution	Contact Time	In Use Span/ Use
Glutaraldehyde(2%) (Glutarex)	Add activator powder / liquid in 5 liter jar and use undiluted	Disinfection: 20-30 mints Sterilization : 10 hours	14 days used for heat sensitive instruments e.g. Endoscopes
HLD – aldehyde based (product preferably should not release formaldehyde gas – so plain formalin solution should not be used) Example product - Bacillocid	Daily use (OT and other critical areas): Add 7 ml of the concentrate per litre of water.* Used once a week (OT only): Add 20 ml per litre of water. Used 2-3 times a week (OT only): Add 10ml per litre of water.* For disinfection of blood body spills: Add 10ml per litre of water (1%)*. <i>*Kindly refer to manufacturer instructions also before use</i>	As per Manufacturer Instruction	For high-level disinfection of surfaces in critical areas. Can also be used for disinfection of blood and body fluid spills on metallic & non-metallic surfaces.

5.Steps of HLD using Chemicals

Glutaraldehyde is recommended to use, as it is the most appropriate chemical disinfectant to provide HLD.

The following steps should be taken:

- First and foremost requirement is to clean the contaminated instruments thoroughly as per instructions. The instruments are then dried thoroughly before placing them in the disinfectant solution
- Completely immerse all items in the HLD
- Record the time and soak the instruments for at least 20 minutes
- Remove the items using sterile forceps or gloves
- Rinse well with boiled and filtered water three times and use immediately or dry with sterile cloth.

6.Reprocessing of Critical & Semi-Critical Medical Equipment Requires High Level Disinfection.

1. Semi-critical medical devices require a minimum of high level disinfection.
2. The disinfectant label indicates that the product is a chemo sterilant or a high level disinfectant (HLD).
3. The HLD is prepared and used according to the manufacturer's instructions specified on the label, MSDS or accompanying product literature.
4. An appropriate chemical test strip specified by the disinfectant manufacturer is purchased and used to test disinfectant minimum effective concentration (MEC) at least daily.
5. Results of all disinfectant MEC testing are recorded in a log.
6. When opened, each container of chemical test strips is checked using a quality control procedure recommended by the manufacturer to verify accuracy.
7. Results of all quality control testing of test strips are recorded in a log.
8. Containers of test strips are dated when opened and not used beyond the shelf life indicated by the manufacturer.
9. There is documentation that the correct HLD solution is used when solution is changed.
10. Devices are completely immersed in HLD for the recommended time.